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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,952	10/31/2001	Stefan Vilsmeier	SCHWP0154US	8866
7590	05/19/2006		EXAMINER	
RENNER, OTTO, BOISSELLE & SKLAR, LLP 1621 Euclid Avenue, Nineteenth Floor Cleveland, OH 44115-2191			DAVIS, DANIEL J	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,952	VILSMEIER ET AL.	
	Examiner	Art Unit	
	D. Jacob Davis	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 February 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,6-16 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,6-16 and 22-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. "The securing element...interact[ing] with bone" is directed to non-statutory subject matter. The device may not be positively recited relative to the bone. To overcome the rejection, Applicants may use phraseology such as, "constructed to," "designed to," "capable of," etc. The following examination on the merits assumes such phraseology is used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-16 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,203,543 to Glossop. Glossop is interpreted in two ways. The first way is demonstrated in figure 1 of this Office action and reads on claims

1-4, 8-16 and 22-25. The proximal threaded section of the securing element interacts with the groove. Centerlines of the operative section and the guide are drawn perpendicular to the device and are offset from each other. Since the proximal side of element 24 is tightly threaded, there is substantially no play between element 22 and element 14. Element 8 comprises a positioning element/reference star. The intermediate section has a diameter greater than a diameter larger than the distal end of the operative section of element 22.

Claims 1, 2, 6, 7 and 13-16 read on the second interpretation of the device as demonstrated in figure 2D. The “operative section that is insertable into bone” does not recite a method step, but is a functional recitation. To meet the limitation, the device must be capable of performing the recitation. The “operative section” is fully *capable* of being inserted into bone. Centerlines of the operative section and the guide are drawn perpendicular to the device and are offset from each other. Element 8 comprises a positioning element/reference star.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,183,474 to Bramlet et al. As illustrated in figure 2, Bramlet discloses an operative section 44 having external threads, and an axially extending groove comprising the proximal lumen of element 22, and a removable securing element 24.

Response to Arguments

Applicant's arguments filed February 17, 2006 have been fully considered but they are not persuasive.

Claims 13 and 24 are rejected in this Office action. The Office action is not made final.

In response to Applicants understanding of Examiner's interpretation of the Glossop reference, the distal portion of both elements 14 and 22 comprise the operative section. The securing element comprises the proximal portion 24 but not the enlarged block head 18. The guide is the lumen of the portion illustrated in the drawing.

The center line of the guide/groove is offset from the center line of the operative section as illustrated by the Examiner.

Applicants traverse that Glossop does not teach, "at least one guide for at least one securing element." The Glossop guide is fully capable of receiving a securing element. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Applicants state, figure 2D of the Glossop reference fails to disclose, "at least one guide for a at least one securing element." Figure 2D shows two guides. At least

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one if not both are fully capable of receiving a securing element. Only the distal portion of the bone screw (and not the entire shaft) forms a part of the operative section.

Claims 22-25 are rejected under 35 U.S.C. 101 as outlined above. Applicants may not claim that the operative section "interacts with bone." However, the proximal portion of the securing element is fully capable of interacting with bone.

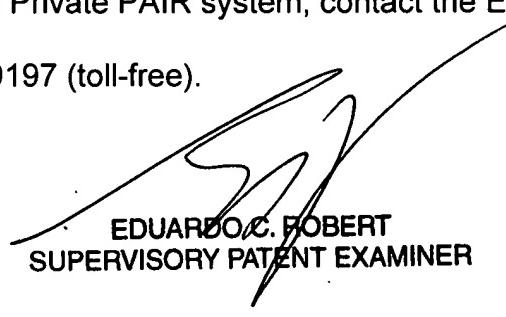
The rejections under 35 U.S.C. 103(a) are withdrawn.

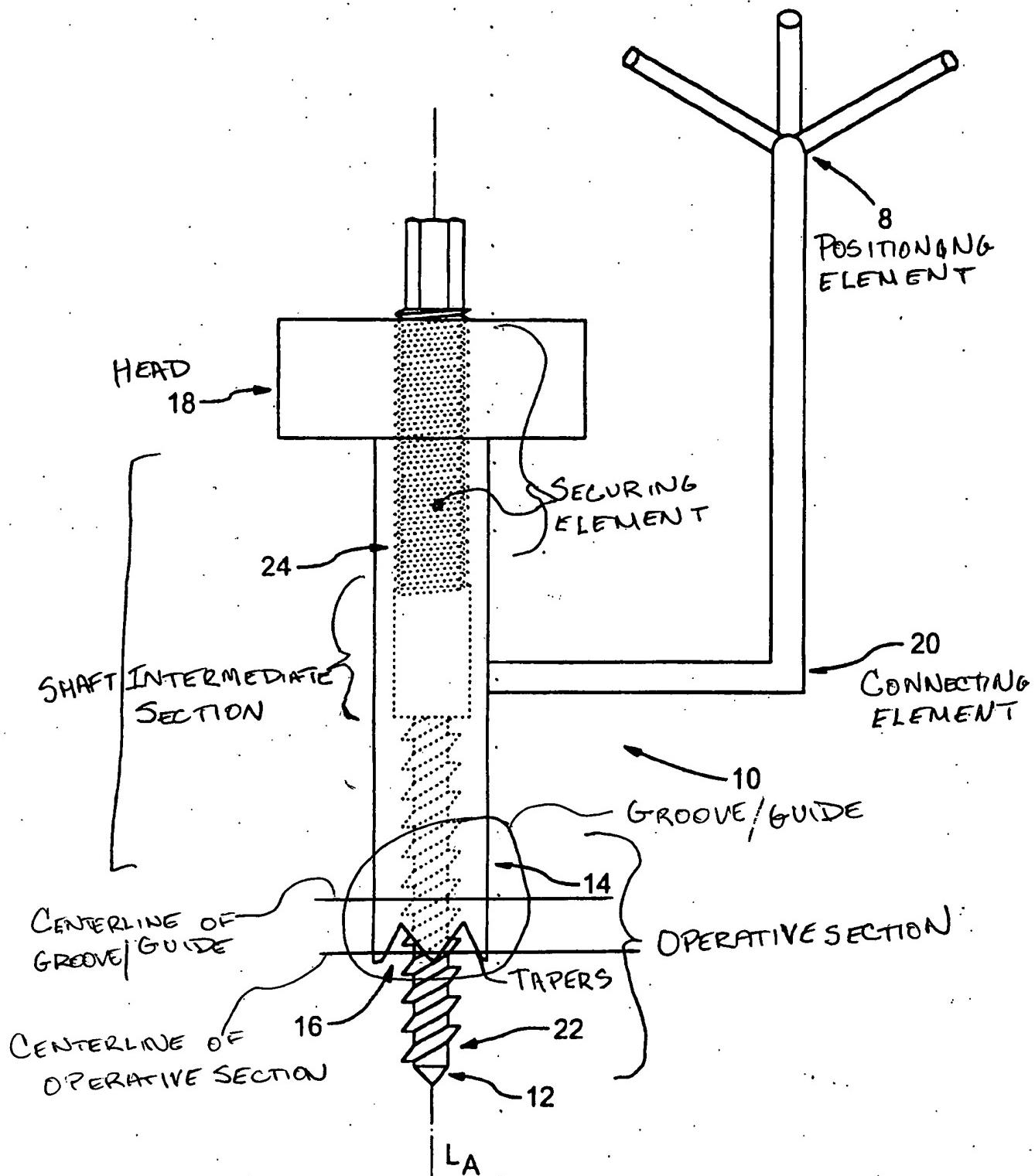
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (571) 272-4693. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

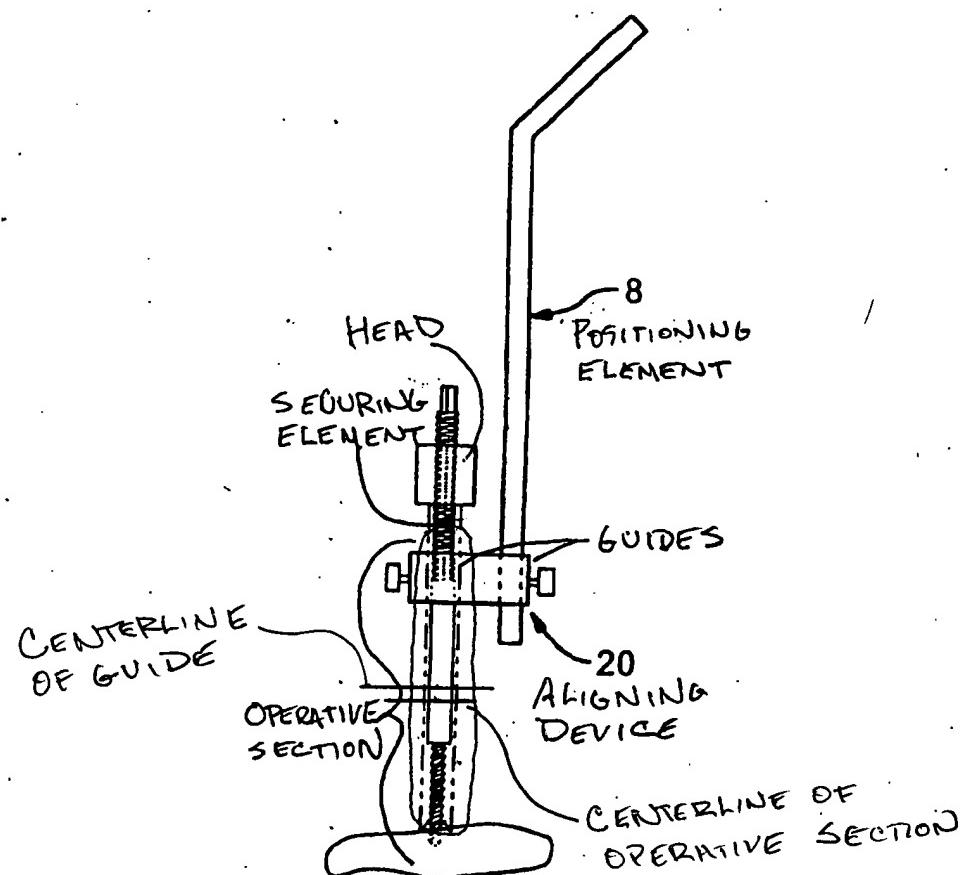
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER



GLOSSOP, FIG.1



GLOSSOP, FIG.2D

